UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,407	09/15/2003	Kenton Zavitz	1907-04-1X	3846

26698 7590 02/26/2007

MYRIAD GENETICS INC.
INTELLECUTAL PROPERTY DEPARTMENT
320 WAKARA WAY
SALT LAKE CITY, UT 84108

EXAMINER	
PARKIN, JEFFREY S	
ART UNIT	**PAPER NUMBER**
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/663,407	ZAVITZ ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *03* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-27* is/are rejected.

7)☒ Claim(s) *20-27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 November, 2006,* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/15/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Office Action

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the communication filed 17 November, 2006, wherein claims 1-19 were canceled without prejudice or disclaimer and new claims 20-27 submitted. Claims 20-27 are currently under examination.

37 C.F.R. § 1.84

Acknowledgement is hereby made of receipt and entry of the drawings filed on 17 November, 2006, which are deemed to be acceptable.

37 C.F.R. § 1.98

The information disclosure statement filed 15 November, 2004, has been placed in the application file and the information referred to therein has been considered.

37 C.F.R. § 1.821-5

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicants are reminded that **ALL** sequences appearing in the **specification** (e.g., see pages 20-23, 25, and 26) and/or drawings must be identified by a sequence identifier (SEQ ID NO.:) in accordance with 37 C.F.R. §

1.821(d). Sequence identifiers for sequences appearing in the drawings may appear in the Brief Description of the Drawings. Applicants are required to review the entire application for compliance and provide appropriate amendments to the specification and/or drawings inserting the required sequence identifiers. Extensive amendments may necessitate the submission of a substitute specification. Any sequences identified in the specification that are not already contained in the sequence listing will necessitate the submission of a substitute sequence listing.

Claim Objections

Claims 20-27 are objected to because of the following informalities: claim 20 references the terms Tsg101, HIV, and the UEV domain. Applicants should clearly identify these regions when they first appear in the claims to avoid any ambiguity or confusion (i.e., the human tumor susceptibility gene 101 (Tsg101); the human immunodeficiency virus (HIV); the ubiquitin E2 variant (UEV) domain). Appropriate correction is required.

35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the subject matter that applicants regard as their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. The claim references the "late domain" of HIV Gag which is vague and indefinite since the precise amino acids in question are not readily apparent. It is suggested that applicants amend the claim language to recite the --late assembly domain of HIV-1 Gag p6-- to avoid any further confusion or ambiguity.

35 U.S.C. § 120

Acknowledgement is hereby made of applicants' domestic priority claim under 35 U.S.C. § 120. This application is a continuation-in-part of PCT/US02/08146, filed 14 March, 2002, a continuation-in-part of U.S. Serial No. 10/223,172, filed 19 August, 2002, and a continuation-in-part of U.S. Serial No. 10/224,999, filed 20 August, 2002. Perusal of these applications failed to provide direct support for the claimed invention. Accordingly, for the purposes of applying art, the effective filing date of the instant application is 15 September, 2003.

35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior

> art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20-22 and 24-26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Pornillos *et al.* (2002) in view of Mhashilkar *et al.* (1995). Pornillos and colleagues demonstrate that the UEV domain of Tsg101 interacts with the late assembly domain of HIV-1 Gag p6 and that this interaction is critical for viral replication. The authors note (see abstract, p. 812) that this binding interaction provides an "attractive starting point for the design of novel inhibitors of virus budding." This teaching does not disclose the preparation of antibodies that are immunoreactive with the UEV domain of Tsg101. However, Mhashilkar and associates provide a panel of monoclonal antibodies and scFvs that are immunoreactive with another HIV-1 viral protein (Tat) and teach that these antibodies are useful inhibitors of HIV-1 replication. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to prepare monoclonal and single chain antibodies, as taught by Mhashilkar *et al.* (1995), that are reactive with the Tsg101 UEV domain, as provided by Pornillos *et al.* (2002), since this represents an attractive target for the development of antivirals.

Claims 23 and 27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Pornillos *et al.* (2002) in view of Mhashilkar *et al.* (1995) as applied to claims 20-26 *supra*, and further in view of Rosen *et al.* (2002). Rosen and colleagues provide art-recognized methods for the production of polyclonal

and humanized immunological reagents. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to prepare polyclonal and humanized reagents, as taught by Rosen *et al.* (2002), that are reactive with the Tsg101 UEV domain, as provided by Pornillos *et al.* (2002), since this represents an attractive target for the development of antivirals.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

19 February, 2007

Notice to Comply	Application No. 10/663,407	Applicant(s) Zavitz, K., *et al.*	
	Examiner Jeffrey S. Parkin	Art Unit 1648	Paper No. 02/19/2007

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR § 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. § 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. § 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. § 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. § 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. § 1.822 and/or § 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. § 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. § 1.821(e).

☒ 7. Other: Applicants are reminded that **ALL** sequences appearing in the **specification** (e.g., see pages 20-23, 25, and 26) and/or drawings must be identified by a sequence identifier (SEQ ID NO.:) in accordance with 37 C.F.R. § 1.821(d). Sequence identifiers for sequences appearing in the drawings may appear in the Brief Description of the Drawings. Applicants are required to review the entire application for compliance and provide appropriate amendments to the specification and/or drawings inserting the required sequence identifiers. Extensive amendments may necessitate the submission of a substitute specification. Any sequences identified in the specification that are not already contained in the sequence listing will necessitate the submission of a substitute sequence listing.

Applicant May Need to Provide:

☒ A substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ A substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. § 1.821(e) or § 1.821(f) or § 1.821(g) or § 1.825(b) or § 1.825(d).

For questions regarding compliance to these requirements, please contact:

- For Rules Interpretation, call (571) 272-0951
- For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patentin Software Program Help @ ebc@uspto.gov.

To Download Patentin Software, visit http://www.uspto.gov/web/patents/software.htm.

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY